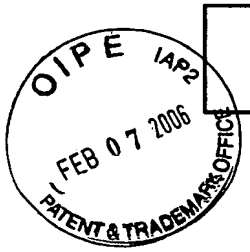
02-08-06

IFW

CASE ON/4-32678A



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February 7, 2006
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

DENT ET AL.

INTERNATIONAL APPLICATION NO: PCT/IB03/04053

FILED: 10 SEPTEMBER 2003

U.S. APPLICATION NO: 10/527,553

35 USC §371 DATE: 9 SEPTEMBER 2005

FOR: COMBINATION OF A) N-{5-[4-(4-METHYL-PIPERAZINO-METHYL)-BENZOY-LAMIDO]-2-METHYLPHENYL}-4-(3-PYRIDYL)-2-PYRIMIDINE-AMINE AND B) A HISTONE DEACETYLASE INHIBITOR FOR THE TREATMENT OF LEUKEMIA

MS: Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The asterisked references were cited in the International Search Report and since copies of said references were forwarded by the International Bureau, only copies of the non-asterisked references are enclosed.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Lydia T. McNally
Attorney for Applicants
Reg. No. 36,214

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7898

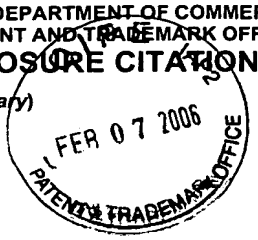
Date: Feb 7, 2006

FORM PTO-1449 (REV. 7-85)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



ATTY. DOCKET NO.
ON/4-32678A
APPLICATION NO.
10/527,553
APPLICANT
DENT ET AL.
FILING DATE
September 9, 2005

Group

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AM						☐	☐
	AN						☐	☐
	AO						☐	☐
	AP						☐	☐
	AQ						☐	☐

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Nimmanapalli et al., "Histone Deacetylase Inhibitor LAQ824 Both Lowers Expression and Promotes Proteasomal Degradation of Bcr-Abl and Induces Apoptosis of Imatinib Mesylate-sensitive or -refractory Chronic Myelogenous Leukemia-Blast Crisis Cells," Cancer Research, Vol. 63, pp. 5126-5135 (2003)
	AS	Grant et al., "Overview--Rational Integration of Agents Directed at Novel Therapeutic Targets Into Combination Chemotherapeutic Regimens," Current Opinion in Investigational Drugs," Vol. 2, No. 11, pp. 1600-1605 (2001)
	AT	Butler et al., "The Histone Deacetylase Inhibitor SAHA arrests cancer cell growth, up-regulates thioredoxin-binding protein-2, and down-regulates thioredoxin," PNAS, Vol. 99, No. 18 pp. 11700-11705 (2002)

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85)
U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

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EXAMINER INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	DA	*La Rosee et al., "Preclinical Evaluation of the Efficacy of STI571 in Combination with a Variety of Novel Anticancer Agents," Blood, Vol. 98(11), pp. 839A (2001)
	DB	*La Rosee et al., "Insights from Pre-Clinical Studies for New Combination Treatment Regimens with the BCR-ABL Kinase Inhibitor Imatinib Mesylate (Gleevec/Glivec) in Chronic Myelogenous Leukemia: A Translational Perspective," Leukemia , Vol. 16, No. 7, p. 1213-1219 (2002)
	DC	*Mellinghoff et al., "The emergence of resistance to targeted cancer therapeutics," Pharmacogenomics, Vol. 3, No. 5, pp. 603-623 (2002)
	DD	*Rosato et al., "Histone deacetylase inhibitors interact in a highly symergistic manner with TRAIL to induce mitochondrial damage and apoptosis in human leukemia cells," Proceedings of the American Association for Cancer Research Annual, Vol. 43, pp. 701 (2002)
	DE	*Almenara et al., "Synergistic induction of apoptosis by the histone deacetylase inhibitor SAHA and the cyclin-dependent kinase flavopiridol in human leukemia cells," Proceedings of the American Association for Cancer Research Annual, Vol. 43, pp. 879 (2002)
	DF	*Yu et al., "Histone deacetylase inhibitors promote STI571-mediated apoptosis in STI571-sensitive and -resistant Bcr/Abl+ human myeloid leukemia cells," Cancer Research, Vol. 63, No. 9 pp. 2118-2126 (2003)
	DG	*Nimmanapalli et al., "Cotreatment with the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) enhances imatinib-induced apoptosis of Bcr-Abl-positive human acute leukemia cells," Blood, Vol. 101, No. 8, pp. 3236-3239 (2003)
	DH	*Grisolano et al., "An activated receptor tyrosine kinase, TEL/PDGF.begta.R, cooperates with AML1/ETO to induce acute myeloid leukemia in mice," Database accession no. 139:228345 abstract & Proceedings of the National Academy of Sciences of the United States of America, 100(16), pp. 9506-9511 (2003)
	DI	
	DJ	
	DK	
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	DM	
	DN	

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